

**NATIONAL INSTITUTE FOR HEALTH AND CARE
EXCELLENCE**

Early value assessment guidance consultation document

**Digitally enabled technologies to support
treatment with weight-management medication
in specialist weight-management services:
early value assessment**

Guidance development process

Early value assessment (EVA) guidance rapidly provides recommendations on promising health technologies that have the potential to address national unmet need. NICE has assessed early evidence on these technologies to determine if earlier patient and system access in the NHS is appropriate while further evidence is generated.

The medical technologies advisory committee has considered the evidence and the views of clinical and patient experts. EVA guidance recommendations are conditional while more evidence is generated to address uncertainty in the evidence base. NICE has included advice in this guidance on how to minimise any clinical or system risk of early access to treatment.

Further evidence will be generated over the next 4 years to assess if the benefits of these technologies are realised in practice. NICE guidance will be reviewed to include this evidence and make a recommendation on the routine adoption of this technology across the NHS.

This document has been prepared for public consultation. It summarises the evidence and views that have been considered and sets out the recommendations made by the committee. NICE invites comments from registered stakeholders, healthcare professionals and the public. This document should be read along with

the [evidence on the NICE website](#) (an EVA report by the external assessment group and an overview of that report).

The advisory committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
- Are the recommendations sound, and a suitable basis for guidance to the NHS?

Equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the recommendations may need changing to meet these aims. In particular, please tell us if the recommendations:

- could have a different effect on people protected by the equality legislation than on the wider population, for example by making it more difficult in practice for a specific group to access the technology
- could have any adverse effect on disabled people.

Please provide any relevant information or data you have about such effects and how they could be avoided or reduced.

Note that this document is not NICE's final guidance on digitally enabled weight-management programmes. The recommendations in section 1 may change after consultation.

After consultation, NICE will consider the comments received. The final recommendations will be the basis for NICE's early value guidance.

Key dates:

Closing date for comments: 24 August 2023

1 Recommendations

1.1 Four digitally enabled weight-management technologies can be used in the NHS while more evidence is generated to support treatment with weight-management medication in adults.

The following technologies can only be used once they have appropriate Digital Technology Assessment Criteria (DTAC) approval:

- Liva (Liva)
- Oviva (Oviva)
- Roczen (Reset Health)
- Second Nature (Second Nature).

1.2 The technology developers must confirm that agreements are in place to generate the evidence (as outlined in NICE's evidence generation plan) and contact NICE annually to confirm that evidence is being generated and analysed as planned. NICE may withdraw the guidance if these conditions are not met.

1.3 At the end of the evidence generation period (4 years), the technology developers should submit the evidence to NICE in a form that can be used for decision making. NICE will review the evidence and assess if the technologies can be routinely adopted in the NHS.

1.4 More research is needed on 3 digitally enabled weight-management technologies to support treatment with weight-management medication in adults. The technologies are:

- CheqUp (CheqUp Health)
- Gro Health W8Buddy (DDM Health)
- Wellbeing Way (Xyla Health and Wellbeing).

1.5 Access to the 3 technologies should be through company or research funding (non-core NHS funding).

Evidence generation and research

1.6 More evidence needs to be generated on the following key outcomes:

- change in weight
- adherence and completion rates
- how the technologies monitor and report adverse events
- impact on resource use, including the number and type of healthcare appointments and cost of medication.

Further important outcomes are described in the [further evidence section](#) of this guidance.

Potential benefits

- **Unmet need:** Digitally enabled weight-management technologies provide specialist weight-management programmes that are another option to support treatment with weight-management medication in adults. They will particularly benefit people who do not have access to specialist weight-management services in their area or who are on a waiting list so are not currently supported by a specialist weight-management programme. Weight-management medication can only be accessed alongside specialist weight-management services. So, these technologies may also improve access to medication.
- **Clinical benefit:** Early evidence suggests that weight loss is similar at 2 years, compared with face-to-face specialist weight-management services.
- **Resources:** The technologies may reduce the demand on face-to-face specialist weight management programmes. This may release resources and increase access or reduce waiting times.
- **Access:** The technologies may provide more flexible access to services for people who are unable to travel or prefer to access services remotely.

Managing risk

- **Clinical assessment:** A full clinical assessment and referral for weight management medication is needed before using these technologies to make sure they are suitable.
- **Multidisciplinary support:** The technologies provide support from a multidisciplinary team (MDT) of qualified healthcare professionals. This includes psychological support and monitoring to reduce the risk of harm, including from disordered eating.
- **Equality:** The technologies may not be suitable for everyone. People who are less comfortable or skilled at using digital technologies are less likely to benefit from them and may prefer a different treatment option.

People with visual, hearing or cognitive impairment, reduced manual dexterity, a learning disability or who are unable to read or understand health-related information (including people who cannot read English) may need additional support to use the technologies.

- **Costs:** Early results from the economic modelling show that the technologies could be cost effective. This guidance will be reviewed within 4 years and the recommendations may change. Take this into account when negotiating the length of contracts and licence costs.

2 The technologies

2.1 Digitally enabled weight-management technologies can be used to deliver specialist weight-management programmes. They can be accessed online or through an app, providing a multidisciplinary programme and in-app support from the programme's multidisciplinary team (MDT) of healthcare professionals. Some programmes offer medication reviews with a prescribing clinician alongside regular reviews with other members of the programme's MDT. Other programmes can collect and share medication adherence data with the NHS team to support weight-management medication prescribing. The frequency of reviews may vary depending on the technology, user preference and stage of the programme. NICE has assessed 7 technologies that can prescribe or monitor weight-management medication, as options for supporting treatment with weight-management medication for adults. The criteria for including technologies in this early value assessment (EVA) and details of each technology are in the [scope on the NICE website](#). The technologies are:

- CheqUp (CheqUp Health)
- Gro Health W8Buddy (DDM Health)
- Liva (Liva)
- Oviva (Oviva)

- Roczen (Reset Health)
- Second Nature (Second Nature)
- Wellbeing Way (Xyla Health and Wellbeing).

During scoping, NICE also identified Juniper (Juniper Technologies UK) as a potential technology. But the company did not respond to requests for information so its eligibility could not be verified and no evidence was identified. So, this technology was not assessed and was not included in the recommendations.

Care pathway

- 2.2 Semaglutide must be used within a specialist weight-management service providing multidisciplinary management of overweight or obesity, including but not limited to tiers 3 and 4 (see [NICE's technology appraisal guidance on semaglutide](#)). Liraglutide for managing overweight and obesity must be prescribed in secondary care by a specialist multidisciplinary tier 3 weight-management service (see [NICE's technology appraisal guidance on liraglutide](#)).
- 2.3 Tier 3 and 4 specialist weight-management services for people with overweight and obesity are defined in [NHS England's guidance for Clinical Commissioning Groups \(CCGs\): Service Specification Guidance for Obesity Surgery \(2016\)](#). The intensity, frequency and variety of support from an MDT of healthcare professionals varies between specialist weight-management programmes. It may be offered in person, remotely by telephone or video call, or as a combination of in-person and remote support. Programmes can last between 6 and 24 months, and the criteria for accessing these services may vary depending on the area and local funding.

The comparator

- 2.4 The comparator is standard care to support treatment with weight-management medication for adults. Standard care includes specialist weight-management programmes (including, but not limited to tier 3 and 4 services). They may be delivered face to face, remotely or as a combination of remote and face-to-face support.
- 2.5 No or delayed treatment is also a relevant comparator. Some people are on waiting lists to access services or have no access at all.

3 Committee discussion

[NICE's medical technologies advisory committee](#) considered evidence on digitally enabled weight-management programmes to support treatment with weight-management medication from several sources, including an early value assessment (EVA) report by the external assessment group (EAG), and an overview of that report. Full details are in the [project documents for this guidance](#).

Unmet need

- 3.1 There is an unequal distribution of specialist weight-management services across the NHS, and in some areas there is no access to them. In areas where there are services, there is an increasing number of people on waiting lists because of limited resources and funding. The clinical experts estimated that 30% to 70% of people do not have access to a local specialist weight-management service. They also estimated that 10% to 30% of people are unable to attend face-to-face appointments because of time commitments or mental health reasons.
- 3.2 Limited access to specialist weight-management services may also limit access to weight-management medication for people who are eligible. Weight-management medication can only be accessed alongside a specialist weight-management programme. The clinical experts explained that if there are no specialist services available, people may be referred to

other weight management services in tier 1 or 2. These services cannot provide weight-management medication and do not offer appropriate support for treatment with medication. They also said that people who cannot access services may go to private providers that are not regulated and could be harmful because there is no wrap around support. The clinical experts agreed that there are limited treatment options for people who cannot access specialist services in their area. The committee concluded that there is an unmet need and access to specialist weight-management services should be improved.

Clinical effectiveness

- 3.3 The evidence suggests that 4 out of the 7 technologies (Liva, Oviva, Roczen and Second Nature) have a potential benefit for adults who are eligible for treatment with weight-management medication. But only 1 published study included people who were taking weight-management medication. There was limited evidence for Gro Health W8Buddy which did not include clinical outcomes, and no evidence for CheqUp and Wellbeing Way.
- 3.4 The evidence base consists of 26 studies reported across 31 publications. Four studies for Second Nature were excluded from the EAG assessment report because they were not considered relevant to the decision problem. But these studies were later considered relevant to the assessment by the committee. The evidence included 1 randomised controlled trial (RCT), 4 non-randomised comparative studies, 1 pilot RCT (that did not compare the technology with standard care), 13 non-comparative studies and 7 unpublished studies that were provided by the companies. The EAG explained that there was limited comparative evidence that reported more weight loss when using the technologies compared with face-to-face specialist weight-management services. The statistical significance beyond 1 year is uncertain, but the evidence suggests equivalence at 2 years. The evidence generally reported weight loss for the technologies

when compared with baseline (for Liva, Oviva, Roczen and Second Nature). The clinical experts agreed that the non-comparative evidence was enough to demonstrate at least equivalent weight loss when the technologies were compared with having no access to specialist weight-management services. The committee heard that longer-term follow up is needed because obesity is a chronic condition.

- 3.5 There is some evidence on programme adherence, programme engagement, health-related quality of life and psychological outcomes. The RCT for Liva reported no difference in the EQ-5D-5L or Short Warwick-Edinburgh Mental Wellbeing Scale scores compared with face-to-face support or with baseline at 6 months and 12 months. The committee concluded that more evidence is needed for these outcomes.

Risk management

- 3.6 Further evidence will be generated while 4 technologies (Liva, Oviva, Roczen and Second Nature) are used in the NHS to address the immediate unmet need, with appropriate risk-management processes in place. The clinical experts and committee stressed the importance of clinical risk management. The companies advised that they have risk-management and safeguarding systems in place. Most of the technologies have monitoring systems to pick up any key words relating to safety or adverse events, as well as regular contact with healthcare professionals. The committee highlighted that there is a lack of evidence relating to how the technologies monitor and report adverse events and limited evidence for people taking weight-management medication. The committee concluded that these technologies can be used as an option to support weight-management medication, if they are used with appropriate safeguarding and with risk-management processes in place, while evidence is generated.

3.7 The clinical experts raised that there is limited information on how multidisciplinary teams (MDTs) are used in the programmes. But, they noted that this is also the case for standard care and that MDTs can vary significantly between weight-management services. The clinical experts also highlighted that a full clinical assessment and referral for weight management medication is needed before using these technologies, to make sure they are suitable. They also noted that the programmes' MDTs must include psychological support because obesity is a complex condition that requires a lot of support. People may have additional co-morbidities and a large proportion of people have mental health issues. They said that it is important to monitor behaviour on restricted diets to minimise the risk of potential harms, such as developing disordered eating. The committee concluded that both psychological monitoring and appropriate referral procedures are important.

Equality considerations

3.8 The technologies may not be suitable for everyone. The clinical experts estimated that 7% to 30% of people may find digitally enabled programmes unsuitable, for example, because of reduced manual dexterity, a learning disability, or less digital knowledge or access to equipment and the internet. The EAG said that the economic model included costs for a tablet computer and monthly internet access, to reduce excluding people because of digital inequality. The committee noted that language could also be a barrier to accessing the programmes. The companies confirmed that most of the included technologies offer the programmes in multiple languages. The clinical experts said that there is a lack of evidence available to identify which groups may or may not be able to access the technologies, or who may benefit the most from them. The committee accepted that some people may need additional support or equipment when using the programmes and agreed that NHS teams should consider providing a tablet computer and mobile internet connection when offering these technologies, to reduce digital inequality.

It concluded that there may be some people who may not benefit from the technologies, but that more data is needed.

Costs and resource use

3.9 The preliminary results of the early economic modelling showed that the technologies are cost effective when compared with face-to-face services. The EAG said that there was limited data to populate the parameters of the model, and that the results are uncertain. Based on the sensitivity and threshold analysis, the biggest factor affecting the results is the estimate of standard care costs used for current tier 3 services. The threshold analysis showed that if standard care costs are reduced by approximately 25%, or the technology costs are increased by 35%, then standard care would become the cost-effective option. The committee concluded that further evidence on clinical effectiveness including health-related quality of life and resource use is needed to reduce uncertainty in the cost modelling.

Evidence gap review

3.10 For the technologies with available weight-loss evidence (Liva, Oviva, Roczen and Second Nature), the key evidence gaps relate to study design and duration, population, comparator, outcomes and decision modelling. The committee concluded that the evidence is limited, and that evidence generation is needed to address the following key evidence gaps:

- Study design and duration: there is limited comparative evidence and no long-term evidence beyond 1 year for most of the technologies, apart from a 2-year study for Liva. The committee and clinical experts highlighted the importance of long-term outcomes to evaluate if weight loss can be maintained.
- Population: Only 1 published study reported the proportion of people taking weight-management medication. The clinical experts and

committee highlighted the importance of generating evidence in this population to ensure that patient safety is monitored appropriately.

There is also a lack of evidence for how different populations, including people who are underserved, engage with the technologies, and which groups may benefit the most.

- **Technologies:** There is limited evidence related to the decision problem for Gro Health W8Buddy, and no available evidence for CheqUp and Wellbeing Way. The committee concluded that further evidence is needed for these technologies.
- **Comparator:** The number of specialist weight-management service providers and the number of people who use the services in the NHS is not known, with limited data on service delivery and MDT composition. The EAG suggested that the NHS Obesity Audit could enable monitoring of these services in the future. The committee concluded that it is important to capture MDT composition and service delivery in further evidence generation because it may also impact the cost-effectiveness results.
- **Outcomes:** There is inconsistency in the outcomes reported in the evidence base. The clinical experts highlighted that the evidence base includes self-reported and clinically measured weight-related outcomes which may introduce bias. The clinical experts agreed that key outcomes should be prioritised to ensure consistency in future evidence generation (see [section 1.6](#)). The committee highlighted the importance of measuring health-related quality of life and psychological outcomes using patient-reported outcome measures such as the EQ-5D, SF-12, SF-36 or PHQ-9.
- **Decision modelling:** There is a lack of direct economic evaluations related to all the technologies. The committee concluded that more direct data is needed for both digitally enabled weight-management programmes and standard care to reduce uncertainty in future economic modelling.

4 Further evidence

Evidence generation

- 4.1 Four technologies (Liva, Oviva, Roczen and Second Nature) can be used in the NHS to address the unmet need, with appropriate safety processes in place. Further evidence will be generated while they are being used. The key outcomes prioritised by the committee for evidence generation are outlined in [section 1.6](#). Other important outcomes include change in body mass index (BMI), programme engagement, rates and reasons for stopping the programme, health-related quality of life and psychological outcomes. Further information will be included in the evidence generation plan.

Research only recommendations

- 4.2 The committee concluded that there was not enough clinical-effectiveness evidence to recommend CheqUp, Gro Health W8Buddy and Wellbeing Way for use in the NHS, other than as part of a research study.
- 4.3 Research should include well-designed and adequately powered studies with appropriate comparators. The key outcomes prioritised by the committee are outlined in [section 1.6](#) and further important outcomes are outlined in [section 4.1](#). Research studies should address the evidence gaps outlined in this guidance to assess the benefit of using these technologies to support treatment with weight-management medications in adults.

5 Committee members and NICE project team

Committee members

This topic was considered by [NICE's medical technologies advisory committee](#), which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the test to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The [minutes of the medical technologies advisory committee meetings](#), which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Additional specialist committee members took part in the discussions and provided expert advice for this topic:

Specialist committee members

Andrew Currie

Consultant in upper gastrointestinal surgery, Epsom and St Helier University Hospitals NHS Trust

Imad Mekhail

Locum GP

Irena Cruickshank

Weight management nurse specialist, Somerset NHS Foundation Trust

Jennifer James

Physiotherapy lecturer, University of Liverpool

Karen Coulman

Research fellow and obesity specialist dietitian, University of Bristol and North Bristol NHS Trust

Rebecca Fahey

Advanced specialist dietitian in weight management, obesity and obesity surgery, Cambridge University Hospitals NHS Foundation Trust

NICE project team

Each early value assessment (EVA) topic is assigned to a team consisting of 1 or more health technology assessment analysts (who act as technical leads for the topic), a health technology assessment adviser and a project manager.

Amy Barr

Health technology assessment analyst

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ISBN:

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